



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,164	07/25/2005	Hermanus Carolus Catherina Karel Bakel Van	101384-1 US	2743

9629 7590 01/16/2008  
MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER
----------

OH, TAYLOR V

ART UNIT	PAPER NUMBER
----------	--------------

1625

MAIL DATE	DELIVERY MODE
-----------	---------------

01/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/518,164

**Applicant(s)**

BAKEL VAN ET AL.

**Examiner**

Taylor Victor Oh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Final Rejection***

**The Status of Claims**

Claims 1-11 are pending.

Claims 1-11 are rejected.

**Claim Rejections - 35 USC § 103**

1. Applicants' argument filed 10/29/07 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.  
This application currently names joint inventors. In considering patentability of

**The rejection of Claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kooistra et al (WO 02/06266 A1).**

The rejection of Claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kooistra et al (WO 02/06266 A1) has been maintained with reasons of record on 7/27/07.

### Applicants' Argument

2. Applicants argue the following issues:
- The Kooistra does not teach the use of N-methylmorpholine as an aid in forming an ester from an acid chloride; it only teaches the use of N-methylmorpholine as an aid in a pivaloyl chloride/ t-butanol reaction.
  - There is nothing to motivate a skilled person to consider using a base recommended for use in one process in a different process.
  - There are significant advantages to using NMM when carrying out the acid chloride reaction on a large scale; the yield was observed to be above 85 % with minimal formation of undesired by-products, whereas experiments carried out using  $\text{Et}_3\text{N}$  gave yields in the range of 40 to 90 % along with the undesired by products.

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first and second arguments, the Examiner has noted applicants' argument. However, the prior art expressly teaches the claimed ester of formula (1) can be obtained from the generated acid chloride intermediate with the alcohol in the followings:

reaction via the acid chloride and t-butanol, under the influence of a base, for example triethylamine ( $\text{Et}_3\text{N}$ ), dimethylamino pyridine (DMAP). The acid chloride can be prepared with the aid of for example  $\text{SOCl}_2$ ,  $\text{POCl}_3$ ,  $(\text{COCl})_2$

and catalyzed by for example dimethyl formamide (DMF) (J. Org. Chem. 35 2429 (1970));

(see from page 5 ,line 24 to page 6, line 2).

Furthermore, Kooistra et al does generally disclose the process for preparing 2-(6-substituted-1,3-dioxane-4-yl) acetic acid derivatives from the generated acid chloride intermediate with the alcohol, especially for the reaction of the acid with pivaloyl chloride and t-butanol under the influence of either NMM or DMAP(see page 6 , lines 15-17) or for the reaction via the acid chloride and t-butanol under the influence of DMAP(see page 5 , line 25). From these teachings, regardless of how each base is used in the process, there is a motivation for choosing an alternative selection of the base, which is within the purview of the skilled artisan and the skilled artisan's knowledge in the art; therefore, it seems reasonable to select either NMM or DMAP as the base suitable for the process for preparing 2-(6-substituted-1,3-dioxane-4-yl) acetic acid derivatives since there is nothing special about using either of them as the base in the absence of an unexpected result. Therefore, applicants' argument is not persuasive to the claimed invention.

Second, with respect to the third argument, the Examiner has noted applicants' argument. However, applicants did not file the declaration of an unexpected result comparing the side-by-side data between the use of the NMM vs. that of DMAP in the process. Without this convincing data, attorney's arguments of unexpected results cannot take the place of evidence in the record. In re DeBlauwe, 736 F. 2d 699, 705, 22 USPQ 191, 196 (Fed. Cir 1984). Therefore, applicants' argument is not persuasive to the claimed invention.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/518,164  
Art Unit: 1625

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

\*\*\*

  
Taylor Victor Oh, MSD, LAC  
Primary Examiner  
Art Unit : 1625

\*\*\*

11/14/08